

## APPENDIX A

### Clean Copy of Amended Claims

1-36 (Cancelled)

37. A method of treating or managing cancer in a patient in need thereof comprising: administering to a the patient a pharmaceutical composition comprising about  $0.5 \times 10^9$  to  $1 \times 10^{10}$  heat inactivated *mycobacterium w*, wherein cancer in the patient is a primary cancer or a secondary (metastatic) lesion thereof selected from the group consisting of multiple myeloma, breast cancer, esophageal cancer, bladder cancer, non small cell lung carcinoma, head & neck cancer, pancreatic cancer, a cancer that metastasizes to bone, liver, or lung, or combinations thereof.

38. The method of claim 37, wherein the method provides symptomatic relief from one or more of pain, decrease hemoglobin, cough, breathlessness, dysphagia, neutropenia or irregular sleep in the patient suffering from cancer.

39. The method of claim 37, wherein the method is for increasing efficacy of radiotherapy or chemotherapy in the treatment of cancer.

40. The method of claim 37, wherein the method is for the reducing side effect of the radiotherapy or chemotherapy.

41. The method of claim 40, wherein the side effects are hematological side effects.

42. The method of claim 40, wherein the side effects are reduced to avoid interruption of chemotherapy.

43. The method of claim 40, wherein the side effects are leucopenia, thrombocytopenia, anaemia, nausea, vomiting or mucositis.

44-46 (Cancelled)

47. The method of claim 37, wherein the heat for inactivating is applied by means of autoclaving.

48-51. (Cancelled)

52. The method of claim 37, wherein the pharmaceutical composition further comprises one or more adjuvants.

53. The method of claim 52, wherein the pharmaceutical composition further comprises a surfactant.

54. The method of claim 53, wherein the surfactant is polyoxyethylene (20) sorbitan monooleate.

55. The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.4% by weight/volume of the pharmaceutical composition.

56. The method of claim 53, wherein the pharmaceutical composition comprises a surfactant in an amount up to 0.1% by weight/volume of the pharmaceutical composition.

57. The method of claim 37, wherein the *Mycobacterium w* is urease negative, or does not hydrolyze polyoxyethylene (20) sorbitan monooleate, or does not produce niacin, and provides a strong positive response to nitrate reduction tests.

58. The method of claim 37, wherein the pharmaceutical composition is administered alone or in combination with other modes of therapy selected from radiotherapy and chemotherapy.

59. The method of claim 37, wherein the pharmaceutical composition is administered by parenteral route.

60. The method of claim 37, wherein the pharmaceutical composition is administered by intramuscular, subcutaneous, or intradermal route.

61-62 (Cancelled)

63. The method of claim 37, wherein the effective amount of pharmaceutical composition is in a unit dosage form comprising from about  $10^9$  to  $10^{10}$  *Mycobacterium w*.

64. The method of claim 37, wherein the pharmaceutical composition further comprises a preservative.
65. (Cancelled)
66. A method of improving the quality of life in a patient suffering from cancer comprising administering to a the patient a pharmaceutical composition comprising about  $0.5 \times 10^9$  to  $1 \times 10^{10}$  heat inactivated *mycobacterium w*, wherein cancer in the patient is a primary cancer or a secondary (metastatic) lesion thereof selected from one or more of multiple myeloma, breast cancer, esophageal cancer, bladder cancer, non small cell lung carcinoma, head & neck cancer, pancreatic cancer, or a cancer that metastasizes to bone, liver, or lung.
67. The method of claim 66, wherein the improvement in quality of life is obtained in the absence of other modes of treatment.
68. The method of claim 66, wherein the improvement in quality of life is obtained with addition of other modes of treatment selected from radiotherapy and chemotherapy.
69. A method of amelioration of symptoms associated with cancer in a patient in need thereof comprising: administering to a the patient with an effective amount of a pharmaceutical composition comprising heat inactivated *mycobacterium w*, wherein the symptoms associated with cancer is selected from the group consisting of pain, decreased hemoglobin, cough, breathlessness, dysphagia, neutropenia and irregular sleep, or combinations thereof.
70. The method of treating cancer according to claims 37, wherein the pharmaceutical composition is administered intradermally.
71. The method of treating cancer according to claims 37, wherein the cancer is superficial bladder cancer and the composition is administered intradermally over the deltoid region.
72. The method of treating cancer according to claims 37, wherein the cancer is muscle invasive bladder cancer and the composition is administered intradermally over the deltoid region.

73. The method of treating cancer according to claim 66, wherein the pharmaceutical composition is administered intradermally.
74. The method of treating cancer according to claim 66, wherein the cancer is superficial bladder cancer and the composition is administered intradermally over the deltoid region.
75. The method of treating cancer according to claim 66, wherein the cancer is muscle invasive bladder cancer and the composition is administered intradermally over the deltoid region.